REMARKS

I. Introduction

Receipt is acknowledged of a final office action dated February 18, 2004. In the action, the examiner rejected claims 1, 2, 17 and 18 as allegedly lacking utility and failing to meet the written description requirement. Reconsideration of this application is respectfully requested.

II. Status of the Claims

In this amendment, applicants amended claim 1 to more clearly define the scope of the claimed invention, and added new claims 46-49. Support for revised claim 1 can be found on page 3 and 15 of the present specification. Support for new claims 46-49 can be found throughout the specification, and on pages 8 and 15 in particular. Upon entry of this amendment, claims 1, 2, 17, 18 and 46-49 will be under examination.

Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

III. Claims Rejected Under 35 U.S.C. § 101

Claims 1, 2, 17 and 18 were rejected under 35 U.S.C. § 101 as allegedly lacking utility. In particular, the examiner stated that "the specification asserts that the claimed polypeptide plays a role [in] ion channel regulation based solely on the structural similarity to stomatin." Furthermore, the examiner contended that the specification "does not disclose a correlation between any specific disorder and an altered level or form of the claimed polypeptide" and "does not predict whether the claimed polypeptide would be overexpressed or underexpressed in a specific diseased tissue compared to the healthy tissue control." Office Action at 6.

Applicants respectfully traverse these grounds for rejection and respectfully request reconsideration and withdrawal of the rejection.

A. The specification supports a specific and substantial utility for the claimed IMPs of the present invention

The IMPs of the presently claimed invention are related to stomatin and the specification discloses that molecules related to stomatin provide new diagnostic or therapeutic compositions that are useful in the treatment of disorders associated with abnormal ion transport or membrane conductance. Specification at 3. Indeed, the IMPs of the claimed invention have "chemical and structural homology with stomatin" and the specification has even identified specific regions of sequence similarity between the claimed polypeptides and stomatin. Specification at 14.

Structural similarity can be indicative of function. To this end, applicants respectfully draw Examiner's attention Steven Brenner et al., *Proc. Natl. Acad. Sci. USA* (1998) 95:6073-6078 (previously submitted November 17, 2003, with the submission under 37 C.F.R. §1.114). Through exhaustive analysis of a dataset of proteins with known structural and functional relationships, Brenner has determined that 30% identity is a reliable threshold for establishing evolutionary homology between two sequences aligned over at least 150 residues, and that 40% identity is a reliable threshold when aligned over at least 70 residues (pages 6073 and 6076). The instantly claimed IMP polypeptides share 33% identity and 60% similarity with residues 96-226 of stomatin. Specification at 14.

Moreover, applicants claimed invention is directed to polypeptides that regulate ion channel activity. Thus, applicants are not claiming peptides that do not have a function but in fact have a specific and substantial utility.

B. The specification discloses a correlation between the claimed IMP polypeptides and specific diseased states

One of skill in the art would know what diseases or disorders are associated with abnormal ion transport or membrane conductance. In fact, the specification describes certain disorders related to improper functioning of ion channels, including hemolytic anemias (e.g., hereditary stomatocytosis, hydrocytosis and xerocytosis) (specification at 27) and that these disorders may be treated by administration of the claimed IMP or a fragment thereof.

In addition, Figure 3 of the instant specification also demonstrates that "IMP serves as a marker for cancerous cells, particularly prostate tumor cells." Specification at 15. The instant application describes that IMP mRNA is expressed in prostate tumor, breast tumor, and

pancreatic tumor libraries (*Id.*) and therefore discloses a correlation between the claimed IMPs of the present invention and "a proliferative cell state." Specification at 27. Thus, the claimed IMP polypeptides of the present invention have a specific and substantial utility as an agent for treating disorders associated with abnormal ion transport or membrane conductance, as well as in the identification of tumor cells.

For the reasons described above, a person of ordinary skill in the art would know how to use the claimed invention for practical benefit. Therefore, the rejection under 35 U.S.C.§112, first paragraph, for lack of utility should be withdrawn.

IV. Claims Rejected under 35 U.S.C. § 112, 1st paragraph

Claims 1, 2, 17 and 18 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to meet the written description requirement. Specifically, the examiner stated that "in order to have proper written description of a sequence, the amino acid sequence itself is required." Office Action at 8. The examiner also stated that "[with regard to] immunologically active fragments, because the fragments themselves are not disclosed, one of skill in the art[] would not understand how to or what to screen." *Id.*. Applicants respectfully traverse this ground for rejection and request reconsideration and withdrawal of the rejection.

A. The specification adequately describes IMP polypeptides which share at least 95% sequence identity with SEQ ID NO: 1

Applicants respectfully assert that the claimed IMP polypeptides are sufficiently described in the present invention. SEQ ID NO: 1 is described in Figure 1 and a skilled artisan, based on the teachings in the art and the instant specification, would know the sequence of an IMP polypeptide that shares at least 95% sequence identity with SEQ ID NO: 1. See specification at 8 and 16. Indeed, the specification describes that certain amino acid residues may be inserted, deleted or substituted within SEQ ID NO: 1 for another amino acid that contains, for example, the same polarity, charge, solubility, hydrophobicity, and hydrophilicity, provided the biological activity of the claimed IMP is retained. Specification at 16. As discussed below, the biological activity of the claimed IMPs can be readily assayed by

employing prior art methods or the methods described in the specification. See, for example, specification at 49-50.

Nevertheless, without acquiescing to the examiner's rejection, and in the interest of expediting prosecution, applicants amended the claims to recite polypeptide variants that comprise at least 95% sequence identity to the polypeptide of SEQ ID NO: 1 and possess ion channel activity.

B. The specification sufficiently describes biologically active and immunogenic fragments of SEQ ID NO: 1.

Likewise, the present specification discloses biologically active and immunogenic fragments of SEQ ID NO: 1. Foremost, one of skill in the art would know what is meant by an immunogenic or biologically active fragment and would know how to assess the "immunogenic" or "biologically active" functionality as recited in the claims. The specification teaches that a polypeptide which retains biological activity has, for example, the ability to regulate ion channel activity, and a polypeptide that has immunological activity is capable of eliciting anti-IMP antibodies.

Furthermore, in addition to prior art methods, a skilled artisan would be able to identify fragments of SEQ ID NO:1 and readily assay the fragments for biological or immunogenic activity by employing assays known in the art as well as the assays described in examples IX and X, respectively. Therefore, biologically active and immunogenic fragments meet the written description requirement.

Nevertheless, in the interest of expediting prosecution, applicants amended the claims to recite "that the biologically active fragment regulates ion channel activity" and that the immunogenic fragment is a fragment of a polypeptide that consists essentially of SEQ ID NO: 1. Support for these amendments can be found on page 3 of the instant specification.

Therefore, for at least these reasons, the present written description rejection should be withdrawn.

CONCLUSION

Applicants respectfully request entry of the present amendment as it does not raise any new issues and if fact, reduces issues for appeal. Additionally, reconsideration of the present application in view of the foregoing amendments and arguments is kindly requested.

It is respectfully urged that the present application is now in condition for allowance. Early notice to that effect is earnestly solicited.

Examiner Yaen is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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